

REMARKS

I. Status of the Claims

Claims 23 and 25-42 are pending in the application and stand rejected, variously, under 35 U.S.C. §112, first and second paragraphs. The specific grounds of rejection, and applicant's response thereto, are set out in detail below.

II. Objections

In response to the objection to the drawings, formal drawings are provided herewith.

In response to the objections to the claims, applicant has amended claims 27, 28, 29 and 31 as suggested. However, it is believed that claims 40 and 41, each of which recites unique preambles, should not be amended as suggested.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 23 and 25-42 were rejected under the second paragraph of §112 as allegedly indefinite. One remaining rejection is that relating to the use of the term "stringent hybridization." Applicant once again traverses.

The term stringent hybridization is well known to those of skill in the art and, as of 1997, hardly needed any particular explanation to those working in this field. Again, applicant directs the examiner to page 29 of the specification, which states that reduced stringency includes up to 55°C. Thus, high stringency would clearly be higher than this figure. The examiner also argues that one must also need to know wash conditions to know stringency. While true, one of skill in the art can select not only temperature, but ionic strength and wash conditions, and still achieve "high stringency."

The examiner argues that a temperature of 56°C does not constitute an accepted “high stringency” condition. No evidence is offered to support this position. If the examiner is providing this opinion based on his own knowledge and expertise in the field, and affidavit under 37 C.F.R. §1.104(d)(2). Moreover, the examiner simply reiterates the circular reasoning that the failure to include specific stringency conditions in the specification means that one of skill in the art cannot define this term.

However, as stated above, this term is well known and the conditions which satisfy this term were also well known at the time of filing, for example, as in Sambrook *et al.* (1989). Specification at p. 16, line 3. In addition, applicant draws the examiner’s attention to page 23, lines 9-16, where salt conditions for hybridizations are set forth. In combination with the disclosure on page 9, lines 20-25, where the temperatures for the hybridization are defined (45-68°C), and pages 17 and 29, where the temperatures for reduced stringency are set forth it should be clear for the skilled artisan that the conditions for a stringent hybridization are the salt conditions of page 23 and temperatures above 55°C. Reconsideration of the rejection is again requested.

The examiner also states that use of the term “derivative” raises indefiniteness issues. Applicants traverse the rejection, but in the interest of advancing the prosecution, the claims have been amended to remove the rejected term.

Next, it is argued that claims 25 and 26 are indefinite in that, while limiting the sequence mentioned in claim 23, “they do not clearly indicate if the fragment or derivative of claim 23 is still encompassed.” Applicants traverse. The claim states precisely what it needs to – that the nucleic acid either encodes SEQ ID NO:2, or comprises the polynucleotide sequence of SEQ ID NO:1 – acknowledged by the examiner to appropriately narrow the scope of the independent

claim. Whether a nucleic acid is characterized as a derivative or fragment is irrelevant so long as it meets the limitations of these claims. Therefore, the rejection is believed to be improper, and should be withdrawn.

Finally, claims 35 and 36 are rejected for the recitation of “relative to an endogenous sequence.” Applicants traverse, but in the interest of advancing the prosecution, an amendment has been offered that removes this language. Reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

A. Written Description

Claims 23 and 25-42 stand rejected under the first paragraph of §112 as allegedly encompassing subject matter not within the possession of applicants at the time of filing. Applicant again traverses.

As discussed previously, the claimed derivatives are those that hybridize to SEQ ID NO:1 under highly stringent conditions and encode a polypeptide having the biological activity of side-shoot formation, petal formation, and abscission zone formation. Thus, it is not the case that “any deletion, substitution or addition” is encompassed. The rejection also is based, at least in part, on the alleged failure of applicant to define the hybridization conditions, which issue is discussed above. Thus, it is believed that the rejection, as it is based on this issue, is improper.

The examiner has also argued that no “deletions, insertions, or point mutations [are] described in the specification ... encoded a protein that retained the activity of SEQ ID NO:2.” However, assuming this to be true, it does not mean that applicants did not possess the subject matter of the rejected claims. It simply means that a working example was not provided; however, it is black letter law that examples are, in fact, *not* required. *In re Borkowski*, 164

USPQ 642 (CCPA 1970). One of skill in the art would not doubt, given the present disclosure, that derivatives satisfying the limitations of the claims, could be created.

The examiner's rebuttal to this line of argument is to note that a method of making a product is not a product *per se*, citing *Fiers v. Sugano*, 25 USPQ2d 1606 (Fed. Cir. 1993). It is also stated that an adequate description of a DNA requires a description of the structure. Of course, there is far more to this issue than this simple statement. In *Fiers*, the point of novelty of the claimed nucleic acid was its sequence, and there were no other features to define the claimed DNA molecule. The court held that *the total absence of such a sequence* precluded a finding of conception for the DNA. Here, the claims do refer to SEQ ID NO:1, and then extend a functional "umbrella" around this sequence based upon the ability to of a nucleic acid to hybridize to SEQ ID NO:1, and to encodes a polypeptide having the biological activity of side shoot formation, petal formation, and abscission zone formation. This is a far cry from the situation raised in *Fiers*, and it is not enough to simply argue that every claimed nucleic acid must be referred to by structure. To the contrary, there are numerous issued patent claims that claim nucleic acids, at least in part, by functional parameters.

In light of the foregoing, applicant submits that the rejection is improper. However, in the interest of advancing the prosecution, the term "derivative" has been deleted from the claims. Thus, applicant respectfully requests reconsideration and withdrawal of the rejection.

B. New Matter

The examiner argues that use of the term "high stringency" constitutes impermissible introduction of "new matter" into the specification. As set out above, this term is well known to those of skill in the art. Moreover, such conditions are clearly differentiated from "reduced

stringency,” which are mentioned *per se* in the application, as discussed previously. Therefore, it is believed that the rejection is improper and should be withdrawn.

C. Enablement

Claims 23 and 25-42 are again rejected under the first paragraph of §112 as allegedly lacking enablement. The examiner argues three main points: (a) the phenotype of wild-type *Ls*-transgenic plants is unknown; (b) there are insufficient examples of derivatives that retain *Ls*-like function; and (c) homologous recombination is not enabled. With regard to the latter issue, claim 37 has been canceled. With regard to the other issues, applicant traverses.

i. Phenotype of Ls Overexpressors

Applicant notes that the examiner admits that the *Ls* gene is involved in side shoot, petal and abscission zone formation. The issue is, apparently, whether the *Ls* gene can be expressed in a plant in such a way as to alter these phenotypes. Applicant again refers the examiner to the previously submitted Theres Declaration. In paragraph 9, it clearly is stated that even in the context of a mutant that lacks normal *Ls* function, overexpression of an *Ls* transgene resulted in “many additional shoots developed from the upper surface of the leaves and leaf petioles ... [suggesting] that overexpression of the *Lateral suppressor* gene leads to the formation of ectopic shoots during leaf development.” The examiner questions, however, whether the increase in shoots was in comparison to wild-type plants, or merely the mutant. In order to further clarify this statement, the newly submitted declaration contains a further statement indicating that the previous declaration meant that there was increased shoot formation as compared to wild-type,

not just the mutant. See paragraph 7. Thus, this would appear to address the examiner's concerns regarding the value of overexpression.

ii. Derivatives With Function

The other issue raised by the examiner – lack of derivatives that retain function – presents a similar situation with regard to enablement. Applicant acknowledges that the specification does not demonstrate derivatives that retain function. However, this is a far cry from establishing non-enablement. One of skill in the art is more than capable of making small deletions, insertions, truncations, fusions, *etc.*, each of which retain the ability to promote shoot formation, petal formation, and abscission zone formation – in fact, the examiner acknowledges as much. Nonetheless, a concern remains, on the part of the examiner, that the example provided in the declaration – an “HA” tagged Ls gene – is insufficient to “enable all derivatives encompassed by the claims.” Applicant's response to this statement is two-fold.

First, the examiner has failed to establish why the evidence provided, along with the knowledge possessed by one of skill in the art, is not sufficient to establish enablement of the claimed invention. It is black letter law that it is not the function of the claims to specifically exclude possible inoperative substances. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 224 USPQ 409 (Fed. Cir. 1984). Nonetheless, where applicants have limited the scope of the claims to the area where operability has not been properly challenged, maintenance of the rejection is improper. *In re Frillette*, 165 USPQ 259 (CCPA 1970); *In re Buting*, 163 USPQ 689 (CCPA 1969). Thus, while there are many *possible* derivatives that lack function, it is particularly improper to reject the claims when, as here, *such inoperative species are specifically excluded from the claims!!*

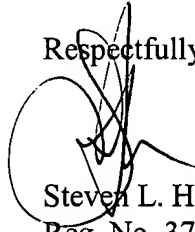
Second, applicant now provides a second declaration from the inventor, Dr. Theres. Therein, an RNAi experiment is described where part of the *Ls* gene has been inserted into a second copy of the *Ls* gene. More specifically, a 5.6 kb XhoI-SnaBI DNA fragment comprising the base pairs 1 to 5570 of cosmid G was subcloned into the binary vector pZP212. This DNA fragment contains the complete open reading frame of the tomato *Lateral suppressor* gene, as well as about 1.4 kb of 5' sequence, and about 2.9 kb of 3' sequence. The *Lateral suppressor* gene was modified by replacing the endogenous promoter with the CaMV35S promoter, with the TMV Ω leader inserted in front of the *Ls* open reading frame. This construct was introduced via *Agrobacterium*-mediated transformation into wild-type tomato plants. Twenty-nine transgenic tomato lines containing at least one copy of the construct were analyzed for side-shoot and flower development: 12 showed wild-type flowers and a strong reduction in side-shoot development; 5 developed a reduced number of petals and showed a strong reduction in side-shoot development; and 2 exhibited a complete suppression of petal development and a strong reduction of side-shoot development. Those plants showing a strong reduction in side-shoot development are very similar to the *lateral suppressor* (*ls¹/ls¹*) mutant, and also showed suppression of abscission zone formation. The remaining 10 lines show either a wild-type phenotype or only a mild reduction in the number of side-shoots.

These results demonstrate that the *Ls* sequences can be used to suppress side-shoot, petal and abscission zone formation in tomato. In addition, it demonstrates that the effects on side-shoot and petal formation can be separated. Finally, though using a full length coding sequence, this RNAi experiment further argues in favor of the utility of fragments of the *Ls* gene. Reconsideration and withdrawal of the rejection is therefore requested.

V. **Conclusion**

In light of the foregoing, applicant respectfully submits that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. Should Examiner Mehta have any questions regarding this submission, a telephone call the undersigned is invited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Steven L. Highlander', is written over a circular stamp or seal.

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